Summary of Safety and Effectiveness Data

I. General Information

Device Generic Name:	Pacing, Temporary, Acute, Internal Atrial Defibrillation System
Device Trade Name:	Response™ CV Catheter System
Applicant's Name and Address:	St. Jude Medical, Daig Division, Inc, 14901 DeVeau Place Minnetonka, MN 55345
Premarket Approval (PMA) Application Number:	P020052
Date of Panel Recommendation:	none
Date of Notice of Approval to the Applicant:	May 7, 2003

II. Indications for Use

Catheter Indication

The SJM Cardioversion Response™ (CV) Electrophysiology Catheter when used with the SJM CV Electrophysiology Extension Cable and SJM Switchbox System is indicated for use in the invasive evaluation of cardiac arrhythmias and can be used for intracardiac cardioversion of atrial tachyarrhythmias.

Catheter Extension Cable Indication

SJM CV Electrophysiology Extension Cables are intended to connect a SJM Response™ CV Cardioversion Electrophysiology Catheter to a SJM Cardioversion Switchbox.

Switchbox Indication

The SJM Cardioversion Switchbox System is intended to connect a SJM Cardioversion "CV" Electrophysiology Catheter and SJM CV Electrophysiology Extension Cable to a compatible cardioverter / defibrillator and EP recording system.

Cardioverter Cables Indication:

The SJM Cardioversion Cable is intended to connect the SJM Cardioversion Switchbox System to a compatible cardioverter.

III. Device Description

The Response™ CV catheter (**Figure 1**) delivers low-energy electric shocks to the heart via the catheter, which is already placed inside the heart as part of a routine EP study. The electrical strength of the low energy internal shocks is comparable to those currently delivered by implantable defibrillators.

The Response™ CV Catheter System (**Figure 2**) consists of the following:

- Response™ CV Catheter
- Response™ CV Extension Cable
- Cardioversion Switchbox (passive)
- Cardioverter Cables
- Electrocardiogram Machine Extension Cable (Decapolar).

Kit configurations will include the system accessory equipment without the catheter, where the catheter is sold separately.

Other commercially available components used with the Response™ CV Catheter System are as follows.

- Electrocardiogram Machine Extension Cable (Decapolar) Daig Supreme™ Decapolar Catheter Extension Cable (510(k) K894500 authorized September 18, 1989)
- External Cardioverter Defibrillator (ECD)
  — Ventritex HVS®-02 (PMA P910023, approved April 30, 1991)
  — CPI Model 2815 VENTAK® (PMA 930035, approved March 10, 1995)
- Electrocardiogram Machine (ECG) (any commercially available system)

Figure 1: Response CV Catheter Schematic

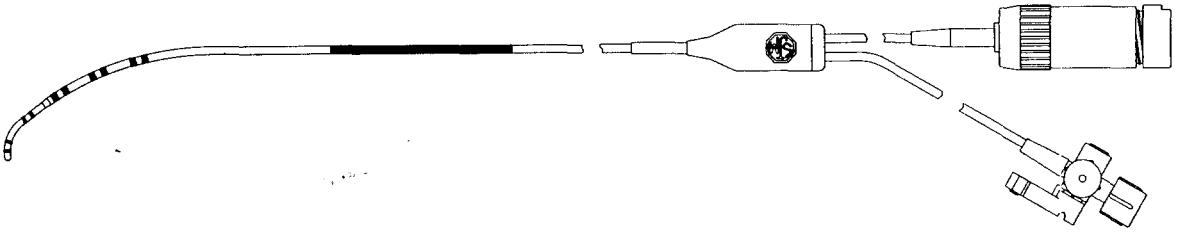
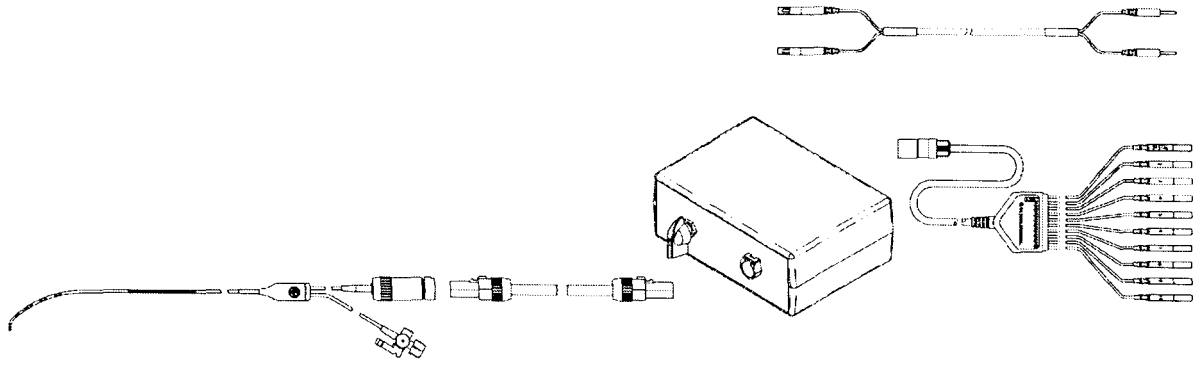


Figure 2: Response CV System Schematic



IV. Contraindications:

Catheter Contraindications

- Electrophysiology studies are contraindicated when arrhythmogenic conditions are present, e.g., electrolyte abnormality, acute ischemia, drug toxicity, hyperthyroidism, etc.
- Electrophysiology studies are contraindicated for patients with unstable cardiac conditions, e.g., acute myocardial infarction, unstable angina, hemodynamic instability, etc.
- Do not use the Response CV system:
  - as an ablation catheter.
  - unless used as part of a SJM Cardioversion Switchbox System.
  - in the left atrium and left ventricle.
  - In patients that cannot tolerate anticoagulation therapies.
  - For cardioversion or defibrillation of ventricular arrhythmias.

Catheter Extension Cable Contraindications

- There are no known contraindications for this device.

Switchbox Contraindications

- DO NOT use this device with a cardioverter designed for transthoracic (external) cardioversion.

Cardioverter Cable Contraindications

None Labeled

Cardioverter Cable Pin Adapters Contraindications:

None Labeled

V. Warnings and Precautions

Please refer to product labeling

VI. Adverse Events

Per the investigational plan, an *adverse event* is defined as clinical occurrences that have a negative effect on the patient's health. Adverse events were classified as major or minor, anticipated or unanticipated.

Device related unanticipated adverse events were defined per the investigational plan as any serious adverse effect on the health or safety, or any life-threatening event, or death, caused by or associated with a device that were not categorized as anticipated.

A. Adverse Events

Adverse events and complications reported in the trial are listed below in **Tables 1 and 2**. Reported Complications and Adverse Reactions. Sixty-one adverse events (AE) were reported for this study as of this summary. Of the sixty-one adverse events, 13 were major and 48 events were minor according to the definitions presented in the protocol. None of the "Major Complications" were attributed by the Principal Investigators to either the Response™ CV catheter or to the control procedure, external cardioversion.

Table 1: Major Adverse Events

Adverse Event	N (unique)	Relationship to procedure	Attribution of AE
Atrial tachycardia	1 (1)	After procedure, prior to discharge	Cardioversion procedure (non-device)
Ventricular fibrillation	1 (1)	During procedure	Cardioversion procedure (non-device)
Nausea/emesis	1 (1)	After procedure, prior to discharge	Cardioversion procedure (non-device)
Hypotension BP 81/54	1 (1)	During procedure	Cardioversion procedure (non-device)
Possible/suspected air embolus.	1 (1)	During procedure	Concomitant invasive procedure
Vaso-vagal episode with blood draw	1 (1)	After procedure, prior to discharge	Other (non-procedure/non-device)
Vaso-vagal response	1 (1)	After procedure, prior to discharge	Other (non-procedure/non-device)
Nausea	2 (2)	After procedure, prior to discharge	Other (non-procedure/non-device)

Adverse Event	N (unique)	Relationship to procedure	Attribution of AE
Nausea/emesis	2 (2)	After procedure, prior to discharge	Other (non-procedure/non-device)
Emesis	1 (1)	During procedure	Other (non-procedure/non-device)
Acute pulmonary edema	1 (1)	After discharge	Other (non-procedure/non-device)
Total	13 (13)		

Table 2: Minor Adverse Events

Safety Minor Complications	Total # per Major Complication Category	Subjects Randomized to Internal Cardioversion, N (%) N total =82	Subjects Randomized to External Cardioversion, N (%) N total =91
Skin Burns	24	-	24 (26.37%)
Response™ CV Catheter Failures	7	7 (8.54%)	-
Hematoma- Subclavian	2	2 (2.44%)	-
Hematoma-Internal Jugular	1	1 (1.22%)	-
Hematoma- Groin	2	2 (2.44%)	-
Rt. Groin Pain	1	1 (1.22%)	-
Heart Murmur	1	1 (1.22%)	-
Severe Bradycardia	1	1 (1.22%)	-
Fever	2	2 (1.22%)	-
Transient Numbness Rt. IJ puncture site	1	1 (1.22%)	-
AF with Rapid Ventricular Response	1	1 (1.22%)	-
Coughing and Wheezing	1	1 (1.22%)	-
Nasopharyngeal Bleeding	1	-	1 (1.09%)
Decreased Oxygen Levels During Procedure	1	-	1 (1.09%)
Difficult Airway Maintenance	1	-	1 (1.09%)
GI Bleed	1	1 (1.22%)	-
Total	48	21 (25.61%)	27 (29.67%)
Unique Patients	43	18 (21.95%)	25 (29.67%)

B. Potential Adverse Effects

Device related anticipated adverse events include as stated in the protocol:

- valvular damage
- conduction system disturbances such as SA node, AV node or His-Purkinje system block
- ventricular arrhythmias
- thromboembolism

- perforation of the myocardium or coronary sinus
- hemotoma or excessive bleeding at the vascular access site

Additional potential adverse effects (in alphabetical order) which may be associated with catheterization and internal cardioversion include:

- anaphylaxis (allergic reaction) with breathing problems, drop in blood pressure and possibly death
- angina (chest discomfort)
- arrhythmia (irregular heartbeat)
- arterial/venous thrombosis (clot formation on the inside wall of the artery at the entry site)
- AV fistula (a communication between the artery and vein at the site of catheter insertion)
- back pain and/or groin pain
- cardiac perforation (hole in the lining of the heart)
- hemotoma formation (bruise or bleeding into body tissue) in groin area
- hypotension (fall in blood pressure)
- infection
- myocardial infarction(heart attack)
- pericardial effusion or cardiac tamponade (collection of blood in lining of the heart)
- pneumothorax (an accumulation of air or gas in the pleural space)
- significant blood loss which may lead to blood transfusion
- thrombotic events including stroke and pulmonary emboli
- unintentional complete heart block requiring a pacemaker
- vessel wall or valvular trauma which may lead to surgical repair

VII. Alternate Practices and Procedures

The present established therapies for treatment of atrial fibrillation and the associated signs and symptoms include pharmacological therapy, surgical procedures including implanting pacemakers, ablation, and internal or external cardioversion.

VIII. Marketing History

The Response™ CV catheter was approved for use in the European Union under a CE Mark and is also available in Australia and parts of Asia. The device has not been withdrawn from marketing for any reason relating to the safety and effectiveness of the device.

IX. Summary of Pre-Clinical Studies

The Response™ CV Catheter and system was tested to ensure that all components function properly, safely, and effectively. Through this comprehensive testing the catheter and the accessory equipment were found to function properly, safely and effectively.

A. Safety and Risk Analysis

A safety and risk analysis of the Response™ CV system was conducted to identify systems hazards and to identify appropriate mitigating actions. This analysis included:

Hazard Analysis

The hazard analysis is used to identify possible hazards from the use of the Response CV system, and documents mitigating actions to minimize risk. A hazard analysis was performed on the Response CV system, including a review of all hazards and mitigating actions, and the residual risk was determined to be acceptable.

Failure Modes Effect Analysis (FMEA)

FMEA was performed on the Response CV system to identify, mitigate and determine the occurrence of any potential design, test, or process issues that could adversely influence the safety and / or performance of the device.

B. Non-Clinical Laboratory Studies (Bench Testing)

Testing has been conducted on the device and on the product manufacturing process. The bench testing challenged the device level and the system level. Compelling evidence of product reliability, safety and effectiveness is summarized below.

Major Device Component Testing Summary

The **Tables 3-5** below list the tests that were conducted on the Response™ CV catheter and system, and provide a summary of the test results. All test criteria are met.

Table 3: List of Tests and Results Summary

Catheter Tests	Acceptance Criteria	Summary of Results (pass / fail)
1. Electrical Continuity	1. Resistance $\leq 4\Omega$	1. 9 of 10 Passed (Pass)[1]
2. Direct Current Resistance and Impedance	2. Resistance $\leq 4\Omega$. AC Impedance at 5,000 hertz must be similar to DC resistance	2. 9 of 10 Passed (Pass)[2]
3. Hi-pot Test (Dielectric Strength)	3. No breakdown or flashover, no signs of damage	3. 10 of 10 Passed (Pass)
1. Surface (Device) Inspection	1. 100% Free from surface defects	1. 9 of 10 Passed (Pass)[3]
1. Dimension Specifications	1. Length of 63 to 67cm	1. 10 of 10 Passed (Pass)
2. Insertion/ Withdrawal through Hemo Valve	2. 100% electrical continuity after 5 rounds of hemo valve insertion	2. 9 of 10 Passed (Pass)[4]
3. Guidewire Insertion/ Withdrawal	3. Guidewire 0.028" to pass in lumen with peak value of < 0.3 pounds	3. 10 of 10 Passed (Pass)
1. High Energy Pulse System	1. 100% must complete 50 shocks at 50J	1. 10 of 10 Passed (Pass)
2. Leakage Current	2. 100% of leaks should be < 100μA	2. 10 of 10 Passed (Pass)

1: One catheter had an intermittent ring to pin connection. It was determined that the pin potting had not cured. The manufacturing process was revised and validated to address this issue. 2: Same a number 1 above. 3: One catheter had minor defect at the coil wire transition in to the catheter due to an extra coil turn. The manufacturing process was revised to address this issue. 4: Same a number 1 above.

Table 4: List of Tests and Results Summary

Catheter Tests	Acceptance Criteria	Summary of Results (Pass / Fail)
• Pressure Decay	• 10 seconds at 1.2psi with decay limit < 0.010psi	• 10 of 10 Passed (Pass)
• Extended High Energy Pulse Integrity	• To failure or 500 shocks at 50J pass visual inspection post test	• 10 of 10 Passed (Pass)
• Hub Leakage	• No bubbles after 5 seconds	• 10 of 10 Passed (Pass)
• Connector separation	• Withstand at least 7.0lbs of force, parts not to separate	• 10 of 10 Passed (Pass)

Table 5: Tests Results Summary of Previous Testing

Catheter Tests	Acceptance Criteria	Summary of Results (Pass / Fail)
1. Joint Bond Pull Strength	1. Force to break > 3.36lbs	1. 30 of 30 passed (Pass)
2. Bond Torque Strength	2. Bond to remain intact while shaft is twisted 3 full times	2. 30 of 30 passed (Pass)
3. External Pressure, Fluid Ingress	3. Maintain electrical continuity after 2 hour blood soak	3. 10 of 10 passed (Pass)
4. Pressure vs. Flow	4. No loss of lumen integrity	4. 4 of 4 passed (Pass)
5. Connector integrity	5. Resistance $\leq 4\Omega$ and no signs of damage to catheter, no leakage current	5. 10 of 10 passed (Pass)
1. Torque Transmission	1. $5in^2$-lbs $\leq (G*J) \leq$ $8in^2$-lbs	1. 30 of 30 passed (Pass)
2. Shaft Bending Strength	2. $0.015in^2$-lbs $\leq (E*I) \leq$ $0.045in^2$-lbs	2. 30 of 30 passed (Pass)
3. Shaft Buckle Strength	3. Maximum load < 0.35lbs	3. 30 of 30 passed (Pass)
1. Corrosion Resistance	1. No sign of corrosion	1. 2 of 2 passed (Pass)
2. Hubs	2. Hub meets ISO 594-1 and 594-2	2. 4 of 4 passed (Pass)
3. Radio-detectability	3. Optical density contrast ≥ 0.1	3. 2 of 2 passed (Pass)
4. High Pressure Test	4. No leaks up to 80psi	4. 10 of 10 passed (Pass)
• Connector Plug/ Unplug force	1. Insertion force ≤ 5.0lbs	• 10 of 10 passed (Pass)

Device Qualification Testing

Each device of the system is tested in accordance to its complexity and proximity to the sterile field as well as how it is used in the system. Testing conducted on each component documents that the component of the Response™ CV system are qualified for safe and effective use in the system. **Tables 6 and 7** summarize the system testing results. All test criteria are met.

Table 6: List of Product Qualification Tests and Results Summary

Catheter Tests	Acceptance Criteria	Summary of Results (Pass / Fail)
1. Visual (Device) Inspection	1. 100% Free from surface defects	1. 60 of 60 Passed (Pass)
2. Dimension Specifications	2. Length of 63 to 67cm	2. 60 of 60 Passed (Pass)
3. Guidewire Insertion/ Withdrawal	3. Guidewire 0.028" to pass in lumen with peak value of < 0.3 pounds	3. 60 of 60 Passed (Pass)
4. Insertion/ Withdrawal through Hemo Valve	4. 100% electrical continuity after 5 rounds of hemo valve insertion	4. 60 of 60 Passed (Pass)
5. Connector Pull Strength	5. 100% of catheters must withstand at least 3 pounds of force and have 100% electrical continuity	5. 50 of 50 Passed (Pass)
1. Electrical Continuity 2. High Energy Pulse System	1. Resistance $\leq 4\Omega$ 2. 100% must complete 50 shocks at 50J	1. 58 of 60 Passed (Pass) [1] 2. 60 of 60 Passed (Pass).

1 Two catheters had an intermittent ring to pin connection. It was determined that the pin potting had not cured. The manufacturing process was revised and validated to address this issue.

Table 7: Summary of Systems Testing

Systems Tests	Acceptance Criteria	Summary of Results (Pass / Fail)
1. Electrical Continuity	1. No shorts or opens	1. 2 of 2 passed (Pass)
2. DC resistance	2. Impedance < 1Ω	2. 11 of 11 passed (Pass)
3. High Energy Pulses	3. 100% must complete 50 shocks at 50J	3. 2 of 2 passed (Pass)
4. Leakage Current	4. ISO 11318 (1996)	4. 2 of 2 passed (Pass)
5. Dielectric Test	5. No breakdown or flashover	5. 2 of 2 passed (Pass)
6. Durability	6. Maintain continuity	6. 500 shocks delivered 1 unit (pass)

C. Biocompatibility Studies

The Response™ CV catheter was found to be biocompatible through biocompatibility testing. The testing profile for the device is a limited contact, under 24 hours, external communicating device with circulating blood contact. Accordingly, specific biocompatibility tests are required and have been determined according to ISO standard 10993-1. The required tests were carried out by an independent third party testing facility according to written protocols. All protocols complied with standard sub-sections of ISO 10993.

D. Sterilization Information

The sterile components of the Response™ CV system (Response™ CV catheter, Response™ CV catheter extension cable) use a validated 100% ethylene oxide (EtO) sterilization method that provides an SAL of 10^{-6}.

E. Animal Studies

One pre-clinical evaluation of the Response™ CV Catheter in a total of 15 dogs was conducted. The purpose of the study was to determine that the device system provided acceptable performance during delivery of cardioverting energy. The study results document that the system is capable of appropriate performance during energy delivery.

X. Summary of Clinical Studies

A. Study Design

The study was an acute, multicenter, prospective, randomized design in which outcomes for the primary study endpoints were compared to a control group using the current clinical procedure, external cardioversion. If the randomized treatment failed, retreatment with the initial treatment (after supplemental medication) or crossover to the alternative treatment group was permitted. The crossover and retreatment data were analyzed separately from the initial randomized treatment data.

Inclusion Criteria:

- Patient is at least 21 years of age.
- Patient has existing atrial fibrillation or is undergoing an EP procedure in which cardioversion is anticipated.
- Patient is a suitable candidate for both internal and external cardioversion.
- Patient or legal guardian has signed a study-specific consent form.

Exclusion Criteria:

- Known abnormal coronary sinus anatomy.
- New York Heart Association functional Class IV (as determined by investigator).
- Spontaneous conversion of chronic AF to sinus rhythm as documented by 48-hour Holter or continuous ECG monitoring.
- Active titration of diuretic medications during 48 hours preceding procedure.
- Prosthetic tricuspid valve or annuloplasty ring (suture repair exempted).

- Repaired atrial septal defect (ASD).
- History of sustained ventricular tachycardia, cardiac arrest, or congenital long QT syndrome.
- Digitalis toxicity.
- Electrolyte imbalance (potassium < 3.5 or magnesium < 1.5).
- Hyperthyroidism.
- Atrial thrombus confirmed by transesophageal echocardiogram.
- Myocardial infarction within proceeding two months.
- Cardiopulmonary surgery within proceeding two months.
- Failure to maintain INR $\geq$2.0 for 4 weeks preceding the procedure for patients with chronic AF unless a TE echo rules out LA/LAA thrombus.
- Pacemaker implanted within the previous three months.
- Pregnant or believes she is pregnant.
- Inadequate washout time (<5 half-lives) for antiarrhythmic medications electively discontinued. Amiodarone is exempted from this requirement.

Study Blind

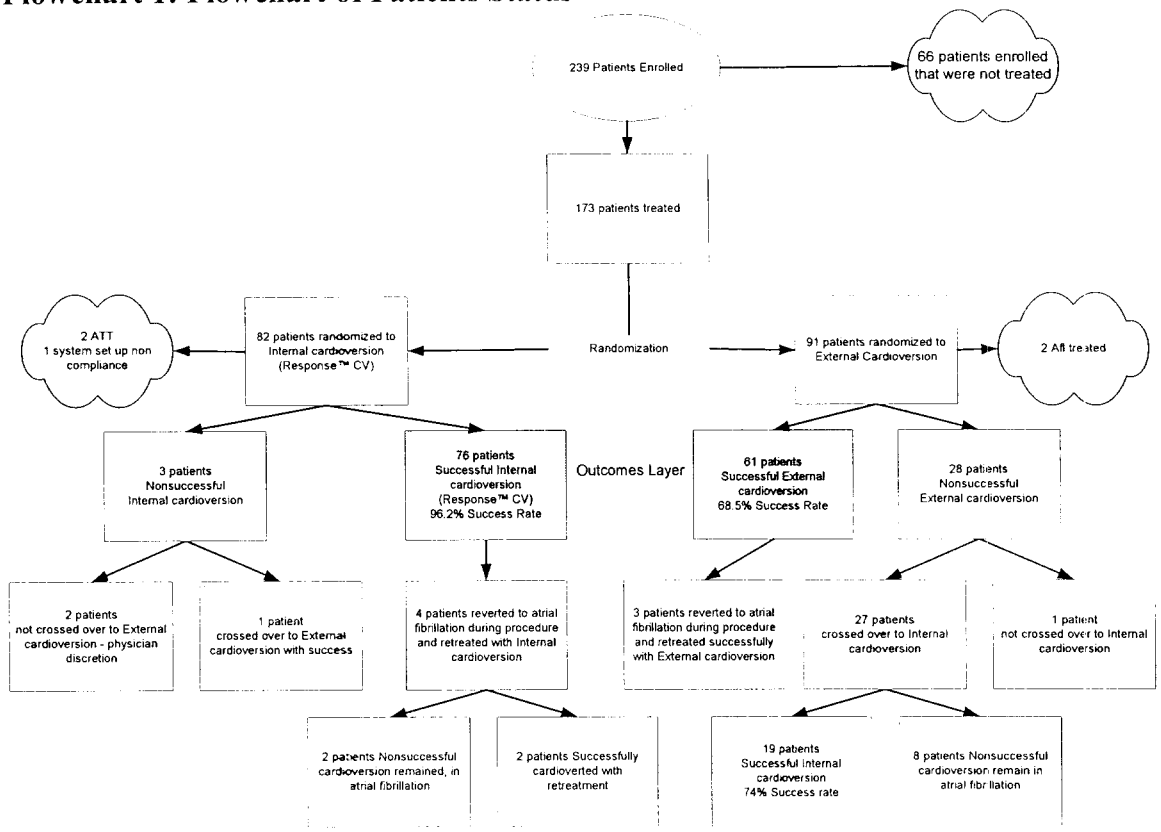
Because of the procedural differences in the test and control procedures the study could not be double blinded. The patient randomization was blinded until immediately prior to the procedure.

B. Clinical Study Results

1. Patient Disposition

The disposition of patients in the study is given in **Flowchart 1**.

Flowchart 1: Flowchart of Patients Status



2. Baseline Demographic Data

An analysis of pre-procedure variables between the two treatment arms, internal cardioversion with Response™ CV (RCV) and External Cardioversion (ECV), shows that the two arms of the study enrolled and treated subjects of similar baseline characteristics. A statistical comparison of these demographics in the respective treatment arms is listed in **Table 8**.

One hundred and seventy-three patients were enrolled and randomized: 82 patient were initially randomized to receive RCV and 91 patients were initially randomized to receive the ECV. The demographic information of the two groups was compared and p-values less than 0.05 were considered statistically significant for demographic comparison.

Table 8: Baseline Characteristics

Variable	Treatment	RCV N total = 82	ECV N total = 91	p-value
Gender	Male	70 (85.4%)	61 (67.0%)	**0.005, Pearson chi-square**
	Female	12 (14.6%)	30 (33.0%)	
AFHX	Chronic	56 (68.3%)	72 (79.1%)	**0.12, Pearson chi-square**
	Paroxysmal	24 (29.3%)	15 (16.5%)	
	No History	2 (2.6%)	4 (4.4%)	
Age	N/A	56.2 +/- 14.1	60.7 +/- 12.7	**0.03, two sample t-test**
Weight	N/A	107.3 +/- 35.9	102.2+/- 26.2	**0.28, two sample t-test**
Height	N/A	178.2 +/- 10.5	173.8+/- 11.5	**0.009, two sample t-test**
EP Procedure	Yes	32 (39.0 %)	23 (25.3%)	**0.05, Pearson chi-square**
	None	50 (61.0 %)	68 (74.7%)	
Pre-existing AF	Induced	13 (15.8%)	12 (13.2%)	**0.62, Pearson chi-square**
	Pre-existing	69 (84.2%)	79 (86.8%)	
Heart Murmur	Murmur	10 (12.6%)	13 (14.4%)	**0.67+, Pearson chi-square**
	None	71 (87.6%)	77 (85.6%)	

3. Primary Effectiveness Endpoint Results

The efficacy analysis provides evidence that the Response™ CV cardioversion rate is equivalent (or nor inferior to) external cardioversion in terms of success rate. A value of 10% is used for the difference parameter (Δ) for the efficacy endpoint. Success is defined as two consecutive cardiac cycles of a non-AF rhythm. To test the equivalence hypothesis, the method of Farrington and Manning (1989) was followed, using the maximum likelihood estimate of variance to perform one-sided z-test.

The efficacy endpoint was measured as the frequency of successful arrhythmia conversion, with a single therapy defined as up to five (5) internal or three (3) external shocks being delivered per arrhythmia episode. Success was defined as two consecutive cardiac cycles of a non-AF rhythm. Failure was defined as uninterrupted continuation of the AF or less than 2 non-AF cycles. In addition, if the Response™ CV Catheter could not be positioned in its targeted location, the coronary sinus (CS), it was also considered a failure. The analysis of the efficacy endpoint is given in **Table 9**.

Table 9: Efficacy

Efficacy **Initial Randomization**	**Response™ CV** **N (%)** **N total = 79**	**External CV** **N (%)** **N total = 89**
Success	76 (96.2 %)	61 (68.5%)
Failure	3 (3.8%)	28 (31.5%)
Success Rate Estimate [95% C.I.]	96.20% [89.30, 99.21%]	68.54% [57.83%, 77.97%]
z –statistic	-5.91	
p-value	1.7E-9	

4. Primary Safety Endpoint Results

To test the equivalence hypothesis, the method of Farrington and Manning (1989) was followed, using the maximum likelihood estimate of variance to perform one-sided z-test, with an equivalence limit of 2%. Out of 82 patients randomized to internal cardioversion, 7 patients developed a major complication and 75 patients were complication-free. The safety results are summarized in **Table 10**.

Table 10: Safety

Major Complications	**Total # per Major Complication Category**	**Subjects Randomized to Internal Cardioversion, N (%) N=82**	**Subjects Randomized to External Cardioversion, N (%) N=91**
Atrial Tachycardia	1	-	1 (1.10%)
Ventricular Fibrillation	1	1(1.22%)	-
Pulmonary Edema	1	1 (1.22%)	-
Possible Air Embolism	1	-	1 (1.10%)
Nausea and Vomiting	6	4 (4.88%)	2 (2.20%)
Vaso-vagal response during blood draw	2	-	2 (2.20%)
Hypotension	1	1 (1.22%)	-
Total	13	7 (8.54%)	6 (6.59%)
Unique Patients	13	7 (8.54%)	6 (6.59%)
Complication-free rate [95% C.I.]		**91.46% [83.2%,96.5%]**	**93.41% [86.20%,97.42%]**
z-statistic		-0.015	
p-value		0.49	

5. Gender Bias Analysis

The gender difference between arms of the study (p=0.005, Pearson chi-square analysis) demonstrates that the internal cardioversion group is 85.4% male, while the external cardioversion group is 67.0% male. This is not clinically significant, when success rates within each arm are compared by gender. As seen in **Table 11** below, the success rates for each arm are comparable for both genders. There was no gender influence on success of either of these two treatment arms.

Table 11: Success Rates by Gender and Randomization

Response™ CV	Success	Failure
Male	66 (96%)	3 (4%)
Female	11 (100%)	0 (0%)
External cardioversion		
Male	41 (58%)	20 (42%)
Female	22 (73%)	8 (27%)

XI. Conclusions Drawn from the Studies

The pre-clinical data establish that the device will withstand the expected conditions of clinical use. The data contained within the clinical study provide sufficient evidence that the Response™ CV catheter is safe and effective for its intended use.

XII. Panel Recommendation

In accordance with the provisions of section 515(c)(2) of the act as amended by the Safe Medical Devices Act of 1990, this PMA was not referred to the Circulatory System Devices Panel, an FDA advisory committee, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by the panel.

XIII. CDRH Decision

Based on a review of the preclinical and clinical testing, FDA believes the safety and effectiveness of this device has been adequately demonstrated. The applicant's manufacturing and sterilizer facilities were inspected and found to be in compliance with the Quality System Regulation (21 CFR 820). FDA issued an approval order on May 7, 2003.

XIV. Approval Specifications

Directions for Use: See labeling.

Hazards to Health from Use of the Device: See Indications, Contraindications, Warnings, Precautions, and Adverse Events in the labeling.

Postapproval Requirements and Restrictions: See approval order.